

Policy Number: 27

Title: Research Conducted at International Performance Sites

Date of Last Revision: 12/27/2004, 11/04/2010, 04/20/2012, 05/01/2016, 09/14/2018, 04/07/2020

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to assure that adequate provisions are in place for research under its jurisdiction conducted at international sites.

- I. **IRB Review of International Research**
 - A. When research is performed in other countries the IRB will ensure that the research meets equivalent levels of protection that would be required domestically taking into account local laws and cultural context.
 1. The IRB follows European Union General Data Protection Regulations for the use of identifiable data within countries of the European Union.
 - B. The IRB will seek the advice of legal counsel, as necessary, to resolve conflicts among applicable laws.
 - C. When the non-US institution or site is a performance site “engaged” in research.
 1. Because UCI holds an assurance with OHRP, any non-US institution or site that will receive federal funds must file an International Federalwide Assurance (FWA) with OHRP.
 2. IRB or equivalent ethical board review must be conducted by a non-US IRB or equivalent ethical board review of the locality where the research will be performed. The UCI IRB must receive and review documentation of approval from the non-US IRB or equivalent ethical board review prior to the commencement of the research at the non-US institution or site.
 - D. When the non-US institution or site is a performance site “not engaged” in research:
 1. When the non-US institution or site has an established IRB or equivalent ethical board review, the Investigator must obtain approval to conduct the research from the site’s IRB or equivalent ethical board review or provide documentation that the site’s IRB or equivalent ethical board *has determined that approval is not necessary for the Investigator to conduct the proposed research at the site.*
 2. When the non-US institution or site does not have an established IRB, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site.
 3. UCI IRB approval to conduct research at the non-US institution or site is contingent upon receiving documentation of approval from the non-US IRB or equivalent ethical board review, or letter of cooperation, as applicable.
 4. It is the responsibility of the UCI Investigator and the non-US institution or site to assure that the resources and facilities are appropriate for the nature of the research.

5. It is the responsibility of the UCI Investigator and the non-US institution or site to notify the UCI IRB promptly if a change in research activities alters the performance site's engagement in the research (e.g., performance site "not engaged" begins consenting research participants, etc.)
- E. When the research is funded by the Department of the Defense, the following requirements apply:
 1. The Investigator must have permission to conduct the research in that country by certification, or local ethics review (or local Naval IRB review if the research is funded by the Department of the Navy).
 2. The Investigator will follow all local laws, regulations, customs, and practices.
 3. These additional safeguards might not be applicable to social-behavioral research involving no more than minimal risk the Investigator should check with the Program Officer.
 - F. The Office of Foreign Assets Control (OFAC) of the US Department of the Treasury administers economic and trade sanctions against specific countries, individuals and entities. The Lead Research should work with the Office of Research – Export Control Officer to confirm feasibility to conduct research in sanctioned countries, as well as obtain the necessary license as applicable.
 - G. UCI IRB can serve as the IRB of Record for an external site engaged in non-exempt research as well as cede IRB review to a non-UCI IRB. **To ensure that appropriate regulatory requirements are addressed as part of the IRB review process, typically, international sites are excluded from these agreements.**

II. IRB Considerations for Approval

- A. For Federally funded research, approval of research for non-US institutions or sites "engaged" in research is only permitted if the non-US institution or site holds an Assurance with OHRP and local IRB or equivalent ethical board approval is obtained.
- B. The IRB will consider local research context (including local applicable laws) when reviewing international studies to assure protections are in place that are appropriate to the setting in which the research will be conducted (See IRB Policy 3). The IRB may require an expert consultant to address issues of local research context if the IRB does not have the expertise or knowledge required to adequately evaluate the research.
- C. The informed consent documents including recruitment materials must be in a language understandable to the proposed participants. The IRB may review the translation and back translation, as applicable, of the foreign language informed consent document. The Investigator must provide the certification or credentials of the translator (See IRB Policy 31).

III. Monitoring of Approved International Research

- A. The IRB is responsible for the ongoing review of international research conducted under its jurisdiction (including continuing review and modifications).
- B. The IRB may require documentation of regular correspondence between the Investigator and the non-US institution or site.
- C. The IRB may require verification from sources other than the Investigator that there have been no substantial changes in the research since its last review as a measure of post-approval monitoring.

References:

45 CFR 46

21 CFR 50 & 56

OHRP, IRB Guidebook, Chapter VI, "Special Classes of Subjects"

71 Fed Reg. 10511 (July 7, 2006)

SECNAVINST 3900.39D, para.6i

DoDD 3216.2, para.4.9

OHRP Link to International Issues: <http://www.hhs.gov/ohrp/international/index.html#regstd>

International Compilation of Human Research Protections – 2010 Edition:

<http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>

Procedure Number: 27.A**Title: Procedure for Research Conducted at International Performance Sites****Procedure:**

This procedure outlines the responsibilities of the UC Irvine (UCI) Institutional Review Board (IRB) and the Investigator for human subjects research conducted at international performance sites.

- I. **Lead Researcher (LR) Responsibilities**
 - A. Researchers must provide the same or equivalent protections to human participants in research conducted in other countries.
 - B. When conducting international research, researchers must be aware of local laws and cultural context in all locations where the research is conducted and comply with local laws and adhere to cultural norms.
 - C. It is the LR's responsibility to provide the following to the UCI IRB for International performance sites "engaged" in research:
 1. A completed Appendix H – International Research, which provides the IRB with adequate information and materials to evaluate local research context for the location in which the proposed research will be conducted.
 2. Protocol documentation that aligns with European Union General Data Protection Regulations for the use of identifiable data within countries of the European Union.
 3. If applicable: a completed Appendix I – Field Work, which provides the IRB with adequate information and materials to evaluate local research context for ethnographic research / field work proposals.
 4. An Office of Human Research Protections (OHRP) approved International Federalwide Assurance (FWA) for the non-US institution or site, if federally funded;
 5. Local IRB or equivalent ethical board approval letter for the proposed research, as applicable; and
 6. A translated informed consent document encompassing all of the required elements of informed consent as well as translated recruitment materials in the language appropriate to the location of the research. An English language back translation of the exact content may be requested by the IRB. The qualifications of the translator must be included in the IRB application or modification request (See IRB Policy 31).
 - D. It is the LR's responsibility to provide to the UCI IRB the following for international performance sites "not engaged" in research:
 1. IRB or equivalent ethical board Approval or Letters of Cooperation.
 - a. When the non-US institution or site has an established IRB, the Investigator must submit to the UCI IRB approval to conduct the research at the "not engaged" site from the site's IRB or provide documentation that the site's IRB has determined that approval is not necessary for the Investigator to conduct the proposed research at the site; or
 - b. When the non-US institution or site does not have an established IRB, the Investigator must submit to the UCI IRB a letter of cooperation demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site.

2. It is the responsibility of the UCI LR and the non-US institution or site to assure that the resources and facilities are appropriate for the nature of the research;
 3. A translated informed consent document encompassing all of the required elements of informed consent in the language appropriate to the location of the research as well as translated recruitment materials must be submitted to the UCI IRB for review and approval, and upon request an English language back translation of the exact content on the translated consent. The qualifications of the translator must be included in the IRB application or modification request.
 4. Adequate information and materials are provided to evaluate local research context in the location in which the proposed research will be conducted.
 5. It is the responsibility of the UCI LR and the non-US institution or site to notify the UCI IRB promptly if a change in research activities alters the performance site's engagement in the research (e.g., performance site "not engaged" begins consenting research participants, etc.)
- II. The LR is responsible for providing to the IRB any reports of correspondence with the non-US institution or site and appropriate documentation of data and safety measures throughout the course of the study, including subject complaints, issues of non-compliance and unanticipated problems involving risk(s) to participants or others (e.g. a breach of participant confidentiality resulting in local ramifications).

II. IRB Responsibilities

- A. The IRB must demonstrate that it has obtained necessary information about the local research context through written material or discussions with IRB Members knowledgeable of the local context or appropriate expert consultants. The level of local knowledge required is based on the degree of risk presented by the research. Extra considerations may include the following to enhance human research protections:
1. The economic prosperity of the area;
 2. The influence of local officials on the population;
 3. Whether the country or area allows foreign visitors;
 4. The nature of the procedures conducted (some may not allow invasive procedures such as in poorer regions);
 5. The literacy rate of the area;
 6. The local legal rights of the population;
 7. How complaints will be reported and to whom;
 8. The relevance of the research to the area's needs; and
 9. The possibility of including officials from the area in the monitoring of the research.
- B. The IRB will review the consent process taking into consideration the following additional issues:
1. Disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts;
 2. Differences in cultural and societal norms;
 3. Differences in the role of women in society;
 4. Differences in the role of family and community in the consent process;
 5. Multiple local languages; and
 6. Literacy level.

- C. The IRB must assure that adequate provisions are outlined for data and safety monitoring keeping in mind that some non-US IRB/EC may not require continuing review of approved research.
- D. UCI IRB approval to conduct research at the non-US institution or site is contingent upon receiving documentation of the non-US performance site's IRB/EC determination, or letter of cooperation, as applicable.

III. **IRB Analyst or Higher Responsibilities**

- A. The Analyst will pre-review the proposed research according to applicable IRB policies and procedures.
- B. The Analyst will assure the required documents are present for adequate review by the IRB.
- C. The Analyst will provide guidance to the LR as needed (e.g., recommending a translation service, verifying OHRP IRB registration and FWA approval for the non-US site).